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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,418	02/19/2002	Maria Dalko	010830-121	9294

7590 01/31/2006

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,418	DALKO ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-13 and 31-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-13 and 31-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/05,1/06*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Request for Continued Examination, amendment and response filed October 13, 2005 has been received and entered into the case. The IDS filed on January 11, 2006 has been received and entered into the case. Claims 18 – 30 are canceled. Claims 1, 6 – 13 and 31 – 38 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. Claims 36 – 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims recite a topical composition comprising a medium which separates the enzyme from the precursor until the time of application. While the specification identifies that each of the instant components may be packaged separately or encapsulated to remain separate, the specification fails to identify a medium which would maintain the components separate until application. Thus the limitation is considered new matter.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 6 – 13 and 31 – 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boussouira in view of Wheeler and/or Berry.

Applicant claims a composition for topical application, comprising an ascorbic acid precursor selected from L-galactono-1, 4-lactone, l-gulono-1, 4-lactone, D-glucorono 1, 4 lactone, D-glucuronic acid, D-mannose, D-galacturonic acid, D-glucose, D-galactose, L-galactose and mixtures thereof; a cosmetically acceptable medium; and at least one enzyme that converts the precursor to ascorbic acid; wherein the enzyme is present at 0.05 – 30%, and the precursor is present at 0.01 – 50%. The enzyme is selected from L-galactono-1, 4-lactone

dehydrogenase, l-galactose dehydrogenase, l-sorbosone dehydrogenase, l-gulono-1, 4 lactone oxidase and mixtures thereof, specifically L-galactono-1, 4-lactone dehydrogenase. Alternatively the enzyme originates from extracts of plants, animals, insects or microorganisms; or is a crude extract, purified enzyme solution, immobilized on a matrix (specifically sol-gel), is solid, liquid, freeze dried, or is in a controlled release device. The enzyme is present at 0.1 – 10%, the precursor is 0.1 – 10% total weight. The enzyme and precursor are packaged separately, or in separate compartments; are encapsulated, microencapsulated or in microgranules; and originates from in vivo or in vitro cells. The composition further comprises ascorbic acid. The medium separates the enzyme from the precursor until the time of application.

Boussouira teaches a composition for topical application, comprising an ascorbic acid precursor, an enzyme that converts the precursor into ascorbic acid and ascorbic acid (abstract, col.4, 9-15). The enzyme is present from about 0.05 – 30%, preferably 0.1 – 10%, of the total composition (col.2 line 59 – 66) and the precursor is 0.1 – 50%, preferably 0.5 – 10% (col.3 line 33-37). The precursor and enzyme are packaged separately so that contact is not made until application (abstract, col.2 line 34-40, col.3 line 57-64) whereby the precursors and enzymes combine to produce active ascorbic acid (col.2 line 41 0 col.3 line 1). The composition further comprises a cosmetically acceptable medium (col.4 line 9-15, 25-31, 53-55). The composition may be encapsulated, microencapsulated, in microgranules (col.4 line 9-12) or gel forms (col.4 line 62-68).

Although Boussouira does not specifically teach the ascorbic acid is derived from in vitro or in vivo cells, the patentability of a product does not depend on its method of production. If

the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Furthermore, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art, thus obvious, to use an enzyme originating from plants, animals insects or microorganisms in liquid, solid or freeze dried form because it was routinely practiced in the art at the time the claimed invention was made.

Boussouira does not teach the composition comprising the claimed enzymes and precursors. However at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use any of the claimed precursors and enzymes because they were well known compounds in ascorbic acid synthesis. In support, Wheeler teaches that ascorbic acid precursors l-galactose and l-galactono-1, 4-lactone are converted to ascorbic acid by l-galactose dehydrogenase (abstract). Specifically Wheeler teaches the most effective precursor of ascorbic acid is l-galactono 1, 4 lactone which is converted by l-galactono 1,4 lactone dehydrogenase (p.365). In addition, Berry teaches ascorbic acid is produced when activity of l-galactose dehydrogenase and l-galactono lactone dehydrogenase is increased (0006) in the presence of ascorbic acid precursors l-galactose and l-galactono lactone (0041). Other ascorbic acid precursors that are converted include l-galactose, l-galactono lactone, d-glucose, d-galactose, d-galacturonic acid, d-glucurono lactone (table 6), d-mannose, l-gulono lactone, and d-glucoronic acid (table 8). At the time of the claimed invention, one of ordinary skill in the art would have

been motivated by Wheeler and/or Berry to use the claimed precursors and enzymes in the composition of Boussouira with a reasonable expectation for successfully obtaining an effective composition for topical application. Absence of evidence to the contrary, the claimed combination of precursors and enzymes do not appear to impart any unexpected benefit or advantage to the resulting composition over the composition in the art, and are therefore rendered obvious for the reasons stated above.

Response to Arguments

Applicant argues that Boussouira does not teach a wide class of enzymes and precursors, but a specific esters which is excluded by the claim. Applicant additionally argues that the reference teaches away from the claimed invention and that the claimed invention requires that the precursor excludes esters. Finally, applicant argues that the supporting references teach pathways of ascorbic acid synthesis in plants and methods for genetically modified organisms, not compositions that produce ascorbic acid when applied.

However, these arguments fail to persuade because Boussouira clearly teaches compositions of ascorbic acid precursors in combination with enzymes will effectively produce the active vitamin (col.2 line 41 – col.3 line 1). While Boussouira specifically identifies a particular type of precursor, the esters, the reference does not teach that these are the only precursors that could be used. Moreover, Boussouira suggests the combination of ascorbic acid precursors and enzymes together in a topical composition. As such, one of ordinary skill in the art would have been motivated to combine other precursors and enzymes with a reasonable

expectation for successfully obtaining the composition with other known ascorbic acid precursors and enzymes known to convert them into vitamins. While the reference clearly indicates the preferred precursors are esters, the reference does not teach away from any particular combination of precursor/enzyme. Regarding the supporting references, these references are relied upon to demonstrate that the instant precursors and enzymes were known in the art.

Furthermore, the claimed precursors and enzymes do not appear to impart any unexpected benefit or advantage to the resulting composition. Absence of evidence to the contrary, the claims stand rejected as being obvious over the references cited above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
January 23, 2006
AU 1651